

PFIZER INC. *et al.*,)
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Plaintiffs,)
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v.) 1:21CV157
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SYNTHON PHARMACEUTICALS, INC.,)
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et al.,)
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Defendants.)
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33), and this matter was transferred to a related multidistrict litigation (“MDL”) action in the United States District Court for the District of Delaware. *See Pfizer Inc. et al v. Synthon Pharmaceuticals, Inc. et al.*, C.A. No. 21-1567-CFC (D. Del. Oct. 20, 2023). The MDL coordinated pretrial proceedings and on October 30, 2023, a conditional remand order from the MDL panel was entered noting that pretrial proceedings had concluded and recommending that the case be remanded to this Court for trial. (ECF No. 39.) The Parties filed a Stipulation of Dismissal with this Court on December 22, 2023. (ECF No. 51.)

II. MOTION TO SEAL

Defendants explain that under the Hatch-Waxman Act, if the brand manufacturer—here the Plaintiffs—initiates a patent infringement suit, the United States Food and Drug Administration (“FDA”) “must withhold approval of the ANDA Product for 30 months (the “30-month stay”) while the parties litigate the validity and/or infringement of the patent.” (ECF No. 49 at 2 (citing 21 U.S.C. § 355(j)(5)(B)(iii)).) FDA regulations provide that “no data or information contained in the application or abbreviated application [ANDA] is available for public disclosure before the agency sends an approval letter.” (*Id.* at 6 (quoting 21 C.F.R. § 314.430(d)(1)) (alteration in original).) Defendants explain that during the MDL proceedings, the Parties agreed to extend the 30-month stay, as reflected in the Status Report and Exhibit D to that report, which is a Stipulation and Order that was originally designated confidential and filed under seal in the MDL because it contains the date to which the Parties agreed to extend the stay. (ECF No. 49 at 3.) Defendants further note that when a redacted copy of what is now Exhibit D was originally docketed in the MDL, the date remained sealed. (*Id.* (citation omitted)).

Defendants request that the 30-month stay expiration date, as set forth in the Parties' Amended Joint Case Status Report, be maintained under seal and that the proposed redacted version of Exhibit D be filed on the public docket, as was done in the MDL proceedings. (*Id.* at 3–4.) According to Defendants, they “have a significant interest in protecting the confidentiality of the stay’s expiration date, and preventing the serious competitive harm that could result from disclosure of this information.” (*Id.* at 1.) Defendants argue that this interest outweighs the public’s interest in full access to these documents. (*Id.* at 1.) Plaintiffs take no position on whether the proposed redacted portions of the Status Report and Exhibit D should be filed under seal and do not claim confidentiality with respect to the 30-month stay expiration date. (ECF No. 46 at 2.)

“[T]he courts of this country recognize a general right to inspect and copy . . . judicial records and documents.” *Nixon v. Warner Commc’ns, Inc.*, 435 U.S. 589, 597 (1978). “It is well settled that the public and press have a qualified right of access to judicial documents and records filed in civil and criminal proceedings.” *Doe v. Pub. Citizen*, 749 F.3d 246, 265 (4th Cir. 2014). “The right of public access springs from the First Amendment and the common-law tradition that court proceedings are presumptively open to public scrutiny.” *Id.* (citation omitted). The common-law, however, “does not afford as much substantive protection to the interests of the press and the public as does the First Amendment.” *Rushford v. New Yorker Mag., Inc.*, 846 F.2d 249, 253 (4th Cir. 1988). “The common-law presumptive right of access extends to all judicial documents and records, and the presumption can be rebutted only by showing that ‘countervailing interests heavily outweigh the public interests in access.’” *Doe*, 749 F.3d at 265–66 (quoting *Rushford*, 846 F.2d at 253). The First Amendment presumptive

right of access, in contrast, extends “only to particular judicial records and documents.” *Id.* at 266 (quoting *Stone v. Univ. of Md. Med. Sys. Corp.*, 855 F.2d 178, 180 (4th Cir. 1988)). The First Amendment right of access may only be restricted upon a showing that such a restriction is “necessitated by a compelling government interest and . . . is narrowly tailored to serve that interest.” *Id.* at 266 (citation and internal quotation marks omitted).

“When presented with a request to seal judicial records or documents, a district court must comply with certain substantive and procedural requirements.” *Va. Dep’t of State Police v. Wash. Post*, 386 F.3d 567, 576 (4th Cir. 2004) (citing *Rushford*, 846 F.2d at 253). Substantively, a district court must “first ‘determine the source of the right of access with respect to each document.’” *Doe*, 749 F.3d at 266 (quoting *Va. Dep’t of State Police*, 386 F.3d at 576). Procedurally, a district court presented with a sealing request must

(1) provide public notice of the sealing request and a reasonable opportunity for the public to voice objections to the motion; (2) consider less drastic alternatives to closure; and (3) if it determines that full access is not necessary, it must state its reasons—with specific findings—supporting closure and its rejections of less drastic alternatives.

Id. at 272. The burden rests on the party seeking to keep information sealed. *Va. Dep’t of State Police*, 386 F.3d at 575. The party seeking to seal must provide specific reasons to support its position. *Id.*

Here, Defendants request to partially seal a status report and request for hearing and an accompanying exhibit. These judicial documents are not related to a dispositive motion, which would trigger the First Amendment right of access. *See Rushford*, 846 F.2d at 253 ([T]he more rigorous First Amendment standard . . . appl[ies] to documents filed in connection with a summary judgment motion in a civil case.”). With respect to the documents at issue in this

case, the Fourth Circuit has “never held that the public has a First Amendment right of access to a pretrial hearing on a non-dispositive civil motion.” *Va. Dep’t of State Police*, 386 F.3d at 580. Therefore, in the absence of any explicit Fourth Circuit guidance, the Court finds that only the common-law right applies, but in these circumstances, the Court would have granted the request to seal under a First Amendment right of access analysis as well. *See Guessford v. Pennsylvania Nat’l Mut. Cas. Ins. Co.*, No. 1:12CV260, 2014 WL 12594127, at *3 (M.D.N.C. Sept. 30, 2014) (finding that the common-law and not the First Amendment right of access applied to documents that dealt with non-dispositive motions and noting that the “same result” would have been reached under the First Amendment analysis).

The common-law presumption of access “can be rebutted if countervailing interests heavily outweigh the public interests in access.” *Rushford*, 846 F.2d at 253. “[T]he common-law right of inspection has bowed before the power of a court to insure that its records are not . . . [used] as sources of business information that might harm a litigant’s competitive standing.” *Nixon*, 435 U.S. at 598. Some of the factors to be weighed in the common-law balancing test include “whether the records are sought for improper purposes, such as promoting public scandals or unfairly gaining a business advantage” and “whether the public has already had access to the information contained in the records.” *Va. Dep’t of State Police*, F.3d at 575 (quoting *In re Knight Publ. Co.*, 743 F.2d 231, 235 (4th Cir. 1984) (internal quotations marks omitted)).

Defendants provide three reasons to support the requested sealing of the “confidential, proprietary, and competitively-sensitive information relating to the extended end of the 30-month stay and potential approval date and launch of Defendants’ ANDA Product found in

the Status Report and Exhibit D.” (ECF No. 49 at 6.) First, Defendants assert that if the extended expiration date were made public, it would potentially cause competitive harm to Defendants. (*Id.*) Second, Defendants assert that the information that Defendants seek to seal is restricted to the extended expiration date of the 30-month stay, and therefore, the limited redaction is “narrowly-drawn to permit full public access to all of the non-confidential information.” (*Id.* at 7.) Third, Defendants assert that the potential harm to Defendants if this sensitive business information were made available to the public greatly outweighs any public interest in its disclosure because the “information regarding the agreed-upon extended expiration of the 30-month stay is not relevant to the public’s trust in the Court and is unlikely to further the public’s understanding of the judicial system.” (*Id.*)

Here, the Court finds that the notice requirement has been satisfied. Public notice of the instant request to seal was given in December 2023, when Plaintiffs filed the Motion to Seal and Defendants filed the Response supporting the motion. (ECF Nos. 46, 49.) No party or member of the public has objected to the motion to seal in this case.

In addition, the Court finds that Defendants’ request is narrow as Defendants only seek to seal the expiration date of the 30-month stay. This information would not normally be accessible to the public and could potentially harm Defendants’ competitive standing or its business interests if released to the public. (*See* ECF No. 49-2 (explaining the “highly sensitive” nature of the 30-month stay expiration date and that if the date were disclosed to a competitor, it would be “especially harmful given that Defendants worked on research and development and given the competitive nature of the pharmaceutical space”).) In light of Defendants’ narrow request for sealing, the Court finds that there is no less drastic alternative.

Furthermore, the Court finds that this information is not needed to understand any decision of the Court as the Parties stipulated to dismissal before the Court made a decision on the Parties' requests for a trial date. Finally, during the MDL proceedings, this same information was designated confidential and filed under seal in the United States District Court for the District of Delaware. *See* Sealed Stipulation, ECF No. 155, *Pfizer Inc. et al v. Synthron Pharmaceuticals, Inc. et al.*, C.A. No. 21-1567-CFC. As discussed herein, there is no basis for this Court to now unseal this information.

After weighing the interests of the Defendants and the public, the Court will permit the sealing of the date that the extended 30-month stay expires, which is contained in the Parties' Amended Joint Case Status Report and Request for Status Conference, (ECF No. 45), and accompanying Exhibit D.

ORDER

IT IS THEREFORE ORDERED that Plaintiffs' Motion to Seal, (ECF No. 46), is **GRANTED**. Specifically, the information that is redacted in the Amended Joint Case Status Report and Request for Status Conference, (ECF No. 45), shall remain under seal.

IT IS FURTHER ORDERED that Defendants shall file an unsealed, redacted version of Exhibit D in accordance with this Memorandum Opinion, within 10 days of the publication of this Order, and the redacted information shall remain under seal.

This, the 23rd day of January 2024.

/s/ Loretta C. Biggs

United States District Judge